Finally, as the technology matures, we might require the provision of x-ray tube current modulation according to patient thickness. Ideally such a feature would make optimal use of the radiation forming images according to an individual's dimensions.

Well, that concludes this presentation and I would like to acknowledge the discussion and comments by my colleagues in the next slide. Thank you very much for your attention.

CHAIRMAN ROTHENBERG: Do we have some questions or comments from the committee? We will start with Ms. Kaufman.

MS. KAUFMAN: Kathleen Kaufman. The pre-patient collimation issue, do we have an evidence that the field sizes have been excessive compared to the receptors?

DR. STERN: Yes. There is a paper by Cynthia McCollough in Medical Physics. I think it was published in 1999. It is one of the references that I cite.

MS. KAUFMAN: Yes, I saw that.

DR. STERN: And that has evidence that the field size might be excessive.

MS. KAUFMAN: On a significant number of units, or --

DR. STERN: She was studying one particular unit.

MS. KAUFMAN: Okay. And how difficult is it to correct that?

DR. STERN: It requires hardware and software, and it is correctable to a certain extent, and it is an issue that we want to look at more carefully.

CHAIRMAN ROTHENBERG: I am going to just comment -- and I am sure that you are aware of this as well, but with regard to the unit that she did study, the situation was somewhat correct. There was actually hardware in place to correct it, but the software was not available at the time of the initial release of the scanners.

And that unit, at least, has been corrected to a certain extent, which has reduced particularly the thin slices. One comment that I

would make is in terms of your near term and longer term, some of your longer term suggestions, a number of these have been already included by at least the major manufacturer for the first multi-slice in the U.S.

And that in the actual information that comes in the manual with the scanner, things like CTDI 100 and methods for conversion are provided, and it is probably somewhat difficult for new users to become familiar with the proper usage.

But a lot of this seems to be already done, and I also have been told by those -- by most of the major manufacturers that they are selling these units in the European Union, and they are required to provide the CTDI W and the DLT.

So a lot of this has already been done and is presented on at least some of the units in this country as well.

DR. STERN: I would like to comment about that. Yes, the European Union has according to the IEC, the first edition of the IEC standard has a display of dose required, in terms of dose life

product and CTDI W.

But unfortunately that standard and its recent update have very ambiguous and unclear definitions. So much so that the values displayed are not consistent for different models or different manufacturers.

A number of medical physicists have approach FDA about this concern. They don't know what the values displayed represent truly. As a matter of fact, I know at one very large facility that I recently visited, they turn off the option of displaying these perimeters, the medical physicists do, because they don't know what they mean.

One of the purposes of developing regulations, FDA regulations, is to make definitions very clear and precise, and crisp. That might be accomplished in a revision of the IEC standard as well.

MS. KAUFMAN: I had a follow-up question of the pre-patient collimator issue. That was one unit at one location; is that correct?

DR. STERN: Yes. It was studied by

Cynthia McCollough probably at the Mayo Clinic.

MS. KAUFMAN: Okay. Because it certainly seems like we need additional data on that to determine how wide occurring that is.

DR. STERN: Exactly. That is exactly so.

MS. KAUFMAN: The other thing is that regarding the next data that you all are collecting. Has there been any effort to go back and compare the data to what the manufacturer had reported?

DR. STERN: Not yet. That is a possibility.

MS. KAUFMAN: I think it would be really interesting to know what we are actually seeing out in the field compared to what the manufacturer reported.

DR. STERN: Yes. Yes, I think that is a good idea.

MS. KAUFMAN: The Handbook of Patient Doses that you are working on, patient tissue doses, when do you think that might become available?

DR. STERN: Our initial projection was that it would be available sometime in the fall of this year, but I think it is looking like hopefully by

the end of this year, by the end of 2001.

CHAIRMAN ROTHENBERG: John.

DR. CARDELLA: I had a question in terms of an analysis of a helical single slice unit, and comparing that to a helical multi-detector unit. Does the typical manufacturer increase the technique factors when it is a multi-detector scan? Is that a necessary part of the scan, or are they running the technique factors at the same level, whether it is helical single slice or helical multi-slice?

DR. STERN: I am not familiar generally with what manufacturers do. They do a number of different things, and they might alter, for example, MAS values when a pitch changes.

I don't know whether or how they change parameters for single or multi-slice systems generally.

CHAIRMAN ROTHENBERG: One of the confusions here is, for example, in the case of -- let's say as an example in the G.E. scanners, the target to detector distance is different, shorter, than the multi-slice than for the single-slice

machines.

So you bring in inverse square changes as well that have to be looked at, as well as the MAS changes.

DR. MARX: I am interested in the issue of the display of the patient dose. I have been a strong advocate of the whole movement towards having dose rate and dose displays in fluoroscopy units available for observation by the physician controlling the radiation beam.

And in that situation that immediate feedback can make a tremendous difference to an individual patient, and this is an entirely different situation, and it seems to me that if there is some record of display, you almost need to keep -- not so much for an individual patient, but for a population of patients undergoing a particular kind of study in that institution, periodic retrospective reviews to see are we within the standards or there is some standard set for what kind of radiation exposures this patient in this weight should get for this kind of exam is real different.

DR. STERN: You are describing a quality assurance program,a nd that is a movement that is going on in Europe right now, and we think it is a good idea. And one of the questions would be were we to proceed with any kind of mandatory regulation, how would we factor that in?

How would we promote quality assurance programs through these regulations through a display regulation, for example.

DR. MARX: In a sense, you would have to have -- instead of just having a display, the display would have to come with some rules, like MQSA or something with --

DR. STERN: Well, perhaps not. Maybe it could be -- the display could be required to be imprinted on a record as an equipment requirement. We can't force people to do things, but we can have certain equipment requirements.

CHAIRMAN ROTHENBERG: Michele.

DR. LOSCOCCO: I would have to agree though with some of the physicists that have come to you. Those displays don't seem to mean anything to

me. They don't correlate to like CPTI and exactly define them.

DR. STERN: That's right, because the standard involved, the IEC standard, Edition 1 and Edition 2, do not precisely define those quantities.

CHAIRMAN ROTHENBERG: I think one question about keeping track of things, I know in our pack system we have got all of the things that appear in the image, the KTVMA, the field size and so on, and the manufacturers, at least their initial attempts to give you these dose indicators based on those settings.

So I don't see any reason why that number could not be stored along with the images. So you would have those records along with all the patients records.

DR. RICE: Well, if we take a look at the European system, they have dose area product meters for fluoroscopy units, and they use that widespread.

DR. STERN: Yes, that's right.

MS. KAUFMAN: I believe you had asked for input from the committee regarding the issue of

issuing a formal notice to facilities.

DR. STERN: Yes.

MS. KAUFMAN: And I would like to encourage FDA to do that, particularly relative to the issue of changing technical factors for pediatric cases.

Frankly, I was really surprised to see that 43 percent of the facilities in the next study were doing that, because I don't think we see that on the units that we are inspecting.

And it is obviously a very easy thing accomplish, and I think people just really have not given that a great deal of thought, and it would seem to me that a formal notice from FDA on that might be very effective.

DR. STERN: Thank you.

CHAIRMAN ROTHENBERG: I guess we will have a further chance to discuss this in our committee discussion time allocation, and so thank you, Dr. Stern, and I think we will proceed with the next presentation by Dr. Gagne, and then we will have heard the full spectrum of digital imaging.

DR. GAGNE: I will be switching gears a little bit and getting away from CT, and maybe the higher exposures there and talk about the digital imaging, where we don't have quite as high exposures. The next slide, please.

What I am going to try to do for you today is to a certain extent revisit some of the themes that Stan visited, and certainly that Tom visited with respect to dose understanding, limitation, efficiency, and display.

And then I am going to describe some concerns that the Agency has related to radiation safety and effectiveness, and in particular the concern that we are going to be talking about here is there a potential for a dose increase and/or reduction.

And I think the jury is still out a bit on that, and I think that Tom made that pretty clear in his presentation, but I will try to explain to you why it is that there are particular positive things about digital imaging that come to the forefront in terms of whether we get a dose increase or a reduction of

patient dose.

And then interestingly I am going to revisit some things that we did way in the past. This is in the '60s and '70s, and talking about imaging system inefficiency.

And lastly as Stan did, I will try to describe for you some of the options, regulatory or otherwise, for dealing with these actual and/or perceived concerns. Next slide, please.

So to get to the nitty-gritty of this then, what are we talking about here with respect to actual and perceived concerns for digital radiography. The idea that has come to the forefront is this equivalence to speed.

There is no equivalence to speed or the self-limitation aspect of screen film for digital radiography. And that is related really to understanding the patient dose, and I will talk some more in detail about that in a second.

And, secondly, are there systems available out there that are inefficient, but the basic question that I am going to try to address is the question of

whether there is any evidence of higher patient radiation exposure with these systems when you compare it to screen film, because they are going to replace screen film as a radiographic modality. Next slide, please.

I will spend a little bit of time just giving a very short tutorial -- and please excuse those of you who are at a much higher level than what I am going to go into here, but just to give you a little bit of an appreciation for the kinds of systems that I am going to be talking about, I will discuss three different kinds of systems -- flat panel imaging arrays, and I will explain that to you in a second.

Dr. Rothenberg pointed out to me that the DR's in some areas represents direct capture radiography, and not digital radiography, and so I will try to explain the nomenclature as I go along here.

When I say DR, I am including these three different types of systems in the DR arena; flat panel imaging arrays, computed radiography systems, and systems that use a CCD camera and are optically

coupled.

There are of course other types of digital radiography systems, and other types of digital systems like digital fluoroscopy that use CCD cameras, and film digitizers, and I am not intending to talk about those types of systems here today.

Now, with respect to the public health concern, what we are talking about here is really a prospective if you want look to a certain extent with respect to digital imaging.

The top thing up there says that in 1999, and it is probably hard for you to read, there were about a hundred installations according to this trade publication of CCD and flat panel based x-ray systems installed.

I really don't have a good figure for you in terms of what it is now, but I am sure that it is has increased a lot. That base does not include CR, and so that installation base is small. It is small for the CCD base lens coupled system, and CR was not included in that number.

So that's why I say to a certain extent we

are talking about a prospective look here. Now, one of the reasons why it has not taken off is a variety of reasons, including soft copy display, but one big piece of it is the retrofit problem.

Digital detectors have certain physical sizes and so on to make them a little bit more difficult to incorporate into a radiography system, and so it is a little bit harder to retrofit the x-ray system and get these up and going.

That is one of the reasons why it has not caught on quite as fast as some people would think. CR, on the other hand, when I described to you, is almost a direct replacement in terms of the consent.

So that is a little bit easier to implement and get into installations. So we are talking about a small installation base here. Next slide, please.

Now, let me just spend a little bit of time here describing the different types of digital radiography systems. Flat panel images, and what I am doing here is I am showing you a side view of one of these images, and just to give you a little bit of a

perspective in terms of the sizes here, the size of the phosphor is in the order of a about a hundred microns, or something like that. Maybe a little bit more than that.

And we are looking at the side of this particular detector, and what we have is an indirect conversion device, is that the energy that is absorbed from the x-ray interaction in the phosphor results in a burst of light photons.

And so if you have a burst of light photons, what you need is some kind of sensing element that is sensitive to light, and so you have a series of photo sensitive storage elements there, or photodiodes that record the image in this particular case for indirect conversion.

For direct conversion systems, still flat panel images, the transducers are made up of a different material, and in this case the energy that is absorbed doesn't give you a burst of visible light photons, but effectively gives you a burst of charged particles.

And in this particular case, what you need

in order to sense that image is a capacitor. You store the charge in a capacitor, and so you have capacitors then that are storing your image. So that is for flat panel images.

Now, here is what they look like from the top, and on the left-hand side is basically a top view of these particular kind of detectors, where you have many pixel elements making up the flat panel imaging array in the order of 3,000 by 2,500 pixel elements.

And the actual size of the pixel elements you see on the right-hand side are in the order of about 140 microns by 140 microns, and as I said, depending on whether you use indirect conversion or direct conversion, you either have a photodiode that is that size, and/or a capacitor that is 140 microns by 140 microns.

So this is one of the main players obviously in digital radiography that is being installed out there right now. Next slide, please.

You also have computed radiography systems, and in a computed radiography system, which you use as a storage phosphor, that basically traps

the absorbed energy in this phosphor, and then it is read out through the use of a laser system and outputs digital data.

So the laser system, if you want, effectively takes the place of the film processor. The idea is the same, and you have about the same number of pixel elements, 2,000 by 2,000, and the pixel element size can be 200 microns or a hundred microns by 200 microns.

So this is another name player associated with digital imaging. Now, lastly, the third one that I am going to talk about today. It is a little hard to see this particular image. The top one is a situation where you have an x-ray phosphor, which is coupled through a series of mirrors and lenses to a CCD camera.

And so you create the digital image then with a high grade, high performance CCD camera. You can also take that phosphor and through a series of fiberoptic tapers connect the light coming off the x-ray phosphor to more than one CCD camera, and that is what is depicted in the second picture here.

Again, the number of pixel elements are about 3,000 by 2,5000; and pixel element sizes of about .14 millimeter by .14 millimeter. Now, that is really my synopsis with respect to the different kinds of systems.

Now, what are the radiation protection and safety issues? There are some characteristics to the screen film systems that provide self-limitation of patient exposure. Now, I don't want to imply that this is a good thing with respect to imaging performance.

It is self-limiting because you are losing imaging performance in these systems, and so as a result, because you are losing imaging performance, it ends up limiting the patient exposure, and I will explain what I mean by that in just a second.

In the concept of a speed number is defined and understood for film screens. That is not the case for digital radiography. There is no self-limitation as in screen film systems, and there really isn't any consensus on speed.

And an additional question of course is

the question that I raised before, which is are there inefficient systems possible. Next slide. Here we have a situation where I am trying to explain what is going on with respect to film screen self-limitation.

On the left-hand side is an imaging task that is representing a large dynamic range. What I mean by that is the amount of radiation that is coming out of the lung area, for example, is high. And then lower down in the lung area is a little bit less.

And then in the area corresponding to the spine, there is very little radiation. So those three arrows then represent a different position in terms of optical density.

Now, this is the output that you get from film screening, and the exposure, and what happens is that you have to be careful when you take a chest radiograph in this case to not under-expose the film.

And what I mean by that is the following. If I under-expose the film, what happens is that those three arrows basically move to the left, and if they move to the left, it becomes very difficult to use the information that is recorded on the film. That

results in a retake.

Now, if I have an over-exposure, the three arrows move to the right. Again, what happens is that the outgoing density gets so dark that you can't read through it, and so you can't use the film.

So interesting because of the poor performance if you want of the film screen in this respect with dynamic range, it essentially limits what the patient exposure is. If you over-expose or under-expose, then you end up with a retake.

But it has that patient exposure consideration, which is a self limiting aspect built into the system. Next slide, please. Now, speed is also defined very precisely for film screening.

In fact, I have given you the definition here in the first bulleted item. The speed is 100 over the exposure and MR to produce an optical density of one.

And so if I have a film screen system, a 400 speed film screen system, what it is basically saying is that it takes a quarter of an MR radiation exposure at the set in order to get an optical density

of one.

A film screen system of 200 would require twice as much exposure, and so that is a very much defined term and defined quite definitely for a film screening.

And the position on the exposure axis then depends on where you are on speed. There are two film screen systems being depicted here on the left-hand side, and if you look at the two arrows going down to the exposure axis, that represents a difference of in exposure and a difference in speed then of a factor of two.

There is a difference like 200 speed versus 400 speed. The higher the speed number translates to a lower patient exposure. Now, if we take a look at DR, I have pictured here the same kind of curve, but now in digital radiography what you are plotting is pixel value versus exposure.

And I have three different curves there for three different gains on the system, and I really should concentrate really on one curve. If you think about the task that we had before, which was the chest

radiograph, and the range of exposures that were associated with that, and what I should have done is put those three arrows on one of these curves.

But what I am trying to show here is the following. If you think about positioning those three arrows with respect to what I showed before in one of the curves, if you move to the right of an exposure, or to the left of an exposure, it just moves up and down the curve.

It doesn't result in a retake anymore, and this is a good thing. I am not trying to say this is a bad thing. This is a positive advantage of digital imaging systems. It lowers the retakes, but it is sort of a double-edged sword if you want, because you can basically operate anywhere you want on that particular curve.

So you don't have the self-limitation on patient exposure that is present on film screen systems. So the question that sort of naturally comes about is once these systems get into a clinic, first of all, what are they set up to, in terms of speed with respect to the film screen that was there before,

and secondly, which way they are moving if they are moving with respect to patient exposure to do a particular diagnostic task.

So that is our first, if you want, concern with these systems. Now, let me spend a little bit of time on inefficiency, and the costs of inefficiency. There was a screening program in the '60s and '70s for cardiopulmonary disease, and there was a need for rapid, cheap, imaging systems to do the screening program.

One of the systems that was designed to do that is a device called a photo fluorographic imaging system, and they were positioned in mobile vans, and went around the country to take chest radiographs.

The way that this system works is that there is an x-ray phosphor there after the patient, and you take the light that comes off of that x-ray phosphor through a lens system, and you record the image on a piece of film. Next slide, please.

Now, there were public health concerns way back then with respect mostly with the low detection rate of the diseases that you were trying to find, but

there was also some concern about the higher patient radiation exposure, versus professional screen film radiography.

And the original Bureau of Radiological Health developed some standard techniques for estimating patient exposure in that case. Next slide, please.

Now, one of the systems that I showed you is CCD based lens coupled system that is trying to look at a large object with a small image recorder. The problem with this kind of system, just like the PFG unit, is that it has low efficiency in terms of coupling the photons, light photons to the recorder, and so you have to be very, very careful when you design one of these systems to overcome that efficiency.

And so there is this aspect of going back to a kind of system that we had seen about 25 or 30 years ago. So what are the options in terms of trying to find out more about the patient reduction or patient exposure reduction, or patient exposure increase here with respect to these systems?

One of the things that is going on right now, which is sort of interesting, is that the next 2001 survey is doing chest radiography, and so we will be getting some data this year particularly attuned not only to film screen, but to digital imaging.

And so we will have some data to compare the two of them on the next 2001 series. Now, there is a movement, and Stan talked about it, and Tom also, associated with diagnostic reference level, knowing what the dose is when you take an image with your modality.

And that movement is in the international arena, and ICRP, and national, in the American Association of Businesses and Medicine, and many others. But to do that you need practical tools for managing the radiation dose levels to patients.

You also need a quality assurance program. There was a good question previously about a quality assurance program with respect to computer tomography. And there was a recent report on CR systems, and basically some of the parameters that one can check on quality assurance programs.

Now, with respect to the diagnostic FDA standard. In the best of all worlds it would be nice to be able to write some performance requirements that include imaging performance, in addition to patient exposure, and we look at this sort of data as an approval process in the 510(k) process, but it is not part of the standard.

Unfortunately, I think this would take a great deal of effort to come to a consensus, in terms of not only what it means, but also what the levels are.

But it may be possible that something like a dose display at the operator's console would help to effectuate this diagnostic reference level concept further than it has gone. So, the next slide, please.

So what I want to talk to you about is the previous slide had several different ways to try to handle this question of whether patient exposure increases or decreases but since TEPRSSC is the radiation standards and safety committee, I am looking for your input with respect to that piece of it.

And so I would switch gears a bit, and

what I am saying is that maybe what we ought to be considering not only for digital imaging, but for all radiographic is to have some sort of dose display at the operator's console for all radiographic equipment.

And in that way you have a much cleaner tie to diagnostic reference level. Now, I understand that there is a lot of practical considerations that we have not totally explored or evaluated yet, and these include things like is this the best way for us to allocate our resources, and what is the effectiveness and alternates, and are there alternatives to that.

And do we have clear concise definitions for the dose descripter. So in summary then, I have gone over the three different types of digital radiography that are present out there, and tried to show to you where the concerns lie with respect to radiation safety, and in particular with respect to the concept of speed and inefficient systems.

And then inefficient systems at the present and revisiting the past, and the potential for exposure reduction or increase is not clear yet; and

I gave you a series of options for dealing with this perceived and actual concern, with one suggested regulatory approach. Thank you.

CHAIRMAN ROTHENBERG: Thank you very much, Dr. Gagne. Is there -- do we have any questions for Dr. Gagne?

DR. LAMBERT: A couple of comments and kind of a general thought to share with you, Bob. Your numbers of x-ray units, digital units, probably is a factor of five greater worldwide than what you have shown there.

So the technology in the last 18 months has really taken off, which I think makes this of greater concern because I am aware that things that are happening in industry that I think we will see this technology moving even faster.

Probably one of the biggest limiting factors today is cost more than retrofitting. But I do have a couple of questions, and I recognize that the regulations are regulations that are looking at protecting the health and safety regarding patient radiation exposure.

You alluded to the digital receptors and digital systems. I feel that we really need to possibly make a revision in the standard, which includes disciplines.

And there are a couple of specific dose related things with detectors that I think that all of us think this needs to be considered. That is, that there may need to be a minimum uniformity that is in the standard for these detectors.

The second is that there needs to potentially be a minimum contrast and noise ratio for the detectors, as well as the minimum signal for noise ratio.

Those last three are very appropriate doses from these various systems. What are your thoughts on those? I think that both recognize some of the difficulties with specifying those, but I would like to hear your thoughts.

DR. GAGNE: Well, I think traditionally we really have not addressed the recorder of the images very much, and we certainly have not addressed it in a diagnostic x-ray standard.

There are no regulations as far as the Rad Health Act is concerned on film screening. So when I said something associated with displaying dose at the operators console, and then I put it in for all of digital radiography, that really goes to the x-ray control manufacturer, and it doesn't go to the digital detector. That is the first point.

Secondly, on the display issue, again with respect to its characteristics, in terms of an x-ray imaging modality, that has never been covered in the standard.

I didn't mention here that there is also approval processes associated if you want on the medical device side, in terms of 510(k)s and PMAs, and so on, and so many aspects associated with display, which I agree with you totally, is very important, are being covered through the pre-market approval process on that side of the shop if you want.

But as far as the diagnostic x-ray standard, I am not sure exactly how we could cover that and make that a piece, because it is not as far as the standard.

But I think it is certainly an area that needs to be addressed and data has come out recently indicating that you really have to have quality assurance programs and acceptance tests, and so on associated with that.

As far as the signal and noise ratio and so on, I think that is really the crux of what I am trying to say, which is the following. And I had a quote in a AAPM treatise in a meeting in Anchorage, Alaska, and CRCP for the conference on radiation control program directors.

And I guess what I am saying is this. If the signal and noise -- if the minimum value for the signal and noise ratio is not good enough the tendency will be to go up that curve, and you will go up that curve, and you will increase the radiation exposure.

Now, we don't have total evidence associated with that, but we are going to get at least a snapshot of that with the upcoming next 2001 survey. So I don't disagree with you that there should be minimum requirements, and maybe that is something that we should really look into, but it would take a little

bit longer to get a consensus on what those values are.

It is a lot harder to set up a standard where you actually are putting performance criteria down than it is to have something like a dose display, for example.

DR. LAMBERT: I might suggest that the 2001 work -- and I think you will see a significant difference between detectors, and there is a very clear relationship between -- and contrasting noise diagnostically, as well as -- probably is going to be more important.

DR. GAGNE: I am not sure if the next 2001 survey has an imaging performance module to it or not. So I would like the other people talk to that.

DR. LAMBERT: I am not referring to an imaging performance, as much as a detector performance.

DR. GAGNE: Well, that is what I mean.

DR. LAMBERT: And that is what I am focusing on, and --

CHAIRMAN ROTHENBERG: I would like to

comment. I think that regardless of whether some of these issues can be incorporated within performance standards, I think there is a tremendous need for education and guidance.

And I want to go back to a statement that Dr. Shope made earlier that in the institutions that are getting these, and I mentioned this to you earlier, getting these units installed, and that when the installer leaves, then things may drift.

I think there is even a more basic problem, and that is that many of the companies that are involved in this detector design and putting together systems don't have traditional experience in radiology.

And they may not even know where to set up the system initially. So the problem is more basic than just once they leave.

DR. GAGNE: I certainly agree totally with that. That was one of the things that I was hoping to get across, is the fact that you can start at a position also which is not where the film screen system you are replacing was. And therefore you could

have an increase in that way.

DR. BALZANO: -- and normally the advantage of going digital is to take care of some of these issues that way. Indeed, right now there is no advantage with the way the technology has been set up. There are clearly levels of imaging performance, and so you can -- and in variation there is a great level of accuracy, and I don't see this as being easy.

So I meant to ask you a question. What is wrong with just getting your film screen image and digitizing it directly? That way you can digitize an image just like --

DR. GAGNE: I guess I wouldn't disagree with you that there are no advantages to the digital imaging modalities that are currently represented. They have tremendously more dynamic range, and if you do things like measure detective quantum efficiency on them, they are very much higher, at least at the lower spatial frequencies.

And then that DQE and a component of DQE, which is noise equivalent quanta, doesn't give out like it does in film screens. So there are definite

situations where the digital imaging is an advantage, because you don't end up having to do a retake if you are off on your conditions, okay?

And so there are definite advantages with respect to digital imaging in that respect. I don't know if I addressed your fundamental question though.

DR. BALZANO: There is a lot of experience -- and 50 years of experience in digitizing an image, and for some reason they have not been put together, and it seems --

DR. GAGNE: But if you have already compromised your image through the film's H and D curve, you are not going to recover it by digitizing it, and that is the advantage of a digital imaging system; is that you don't compromise it at the front end.

In order to get the dynamic range that is present in a digital imaging system, you might have to use four different screen film systems, all with different speeds, in order to get that dynamic range.

So there is that very definite advantage with respect to digital imaging. I was trying to

present it as saying, yes, there is that advantage that is built in there, but it is sort of a double-edged sword, in that that means that you can get prettier images and not have to worry about retakes, et cetera, et cetera, you know.

And by the same token, you could get images that use less exposure possibly, and have patient exposure and still be able to do the diagnostic test. That is the prime consideration, of course.

CHAIRMAN ROTHENBERG: I think another consideration that is driving all of this is that the people want the imaging to be electronic, and to utilize them in distributed institutions, and keeping track of images, and storage, and so on.

And that is the major thing that really is driving all these detectors for what used to be the traditional radiographic techniques, and to bring that in with the rest of the digital imaging systems, such as CT, MR, and --

DR. BALZANO: By digitizing the film --

CHAIRMAN ROTHENBERG: but then it is a

multiple step process, which is much less efficient in terms of time in dealing with patients.

DR. LAMBERT: With respect to film systems, I think that film systems were optimized a long time ago, and there is a standard there that works very well. And if you went back and said, oh, Dupont, or Kodak, who is making this film system, if you went back to them and said that there is no problem if you overexpose the patient. It is not a problem.

They would redesign the film to have a great deal more latitude, and you will be able to digitize that film electronically without a problem. Now, I only want to make one other comment, and that is with respect to these flat panel imaging, and especially the capacitor type systems, and the photo dial tech systems.

These systems, the basic physics, and understanding of the signal noise, was treated in the 1950s by Dr. Albert Rose at RCA on a theoretical basis. And you can show on a theoretical basis, and on a practical basis, that the lower limit sensitivity

was not as good as the film systems.

So what you have to go back and look at ti say take a look at this plot that you have on your DR speed for the digital system, and if you show a linear curve, these things with a proper understanding of the system, can be quantitative -- and I believe what you will find is that the bottom end never comes into sensitivity.

DR. GAGNE: There is no question about that, because the electronic noise starts to predominate down there.

DR. LAMBERT: This seems like it should be made very -- somehow the people using the systems are saying that I have more latitude as it is a linear system, and it is possible.

But what we are really saying is that we don't care how much exposure the patient gets if I am going to adopt that type system all the time. So that the name of the game has sort of changing just because we want the image to be digital, that we are now allowing the patient to be exposed at a higher level. And I think that we have to be very careful in that

regard.

DR. RICE: With the conventional system, you have x-rays that produce light and that scatters, and so that reduces the clarify of the image. With a digital system, you have direct conversion, and with direct conversion systems, you should have more of a finite clearer reproductive image.

DR. LAMBERT: I think they that are both scattering light from phosphor and --

DR. GAGNE: No, no, I tried to explain that there are two manifestations of these that are digital imaging systems. One of them is a transducer amorphous selenium, and in that particular case what we are talking about is charged particle transfer and capacitors doing the image storage.

DR. LAMBERT: And that is the very system that Albert Rose treated in 1954 theoretically, is the photo conductor charge capacitor system.

DR. RICE: But there is no standard. There is no light. So it is a direct conversion.

DR. LAMBERT: I understand, but there is a space charge limited issue that limits the basic

fundamental sensitivity of the system. You have to have a voltage to operate it, and based upon that voltage, you can predict the space charge limitations.

DR. GAGNE: I am not sure how much technical detail to get into, but I certainly can make some comments about Albert Rose.

CHAIRMAN ROTHENBERG: It is an important issue that you showed, but you didn't state explicitly with most of these systems, and that is that the spatial resolution is far more limited than it is with the film screen systems we have been using.

DR. GAGNE: Well, that's true, but I would never describe the imaging performance only with spatial resolution. I would use detective quantum efficiency. You know, I am involved in the 510(k) review process of these devices, and there we make comparisons, in terms of detective quantum efficiency, which incorporates not only resolution, but noise and other aspects of the systems' performance.

And you see the direct comparison there between film screen and the systems, and they outperform film screen in certain areas, and in other

areas they don't.

And in one of the areas that they don't is obviously resolution. Yes, that is correct. But they outperform in terms of DQE at low spatial frequency, and they have a lot more dynamic range

DR. NELSON: I would like to move away from the technical questions and ask a more pragmatic one, which is that it looks like you think a dose display at an operator's console would somehow solve these problems. And my question to you is how the operator will use this information.

DR. GAGNE: Well, it really has to be incorporated into a total program. I think Dr. Marx pointed out before that having a display there in and of itself doesn't amount to anything, but if you had a display there, and in addition to that you promote and promulgate good quality assurance programs, and good feedback in terms of these reference dose levels in terms of where facilities stand with respect to the norm, with respect to others, et cetera, then I think it means something.

And so I am not saying that simply

providing the dose number is an end of itself. You have to have a lot more than that.

DR. NELSON: And I guess my other question is that I realize that this is a little bit beyond the scope of the FDA, but it seems like it might not be unreasonable for patients to know how much they are carrying around of radiation exposure they had, and collecting that sort of data.

DR. GAGNE: Talking about revisiting the past, and, Orhan, you can comment if you want.

SECRETARY SULEIMAN: Well, you saw me laughing. I mean, years ago we came up with an x-ray card that patients were supposed to carry around and keep track of all the technical data. So that is what I was chuckling about.

DR. NELSON: I don't think that is practical, but certainly within an institution one could -- for example, when people get radiation therapy for cancer, we calculate the number of Rads they receive to a certain area, and once they get to a certain dose, they don't get radiation to that area anymore. Something along that line.

SECRETARY SULEIMAN: I think the trend -- and as I was mentioning to some people earlier on, in the history of this organization, we didn't quite have a monopoly on the expertise, but we did have quite a proportion of it.

Now I think there is a lot of expertise outside the agency as well. I think this reference value concept that has been touted around, it is not just like the 1950s. In the 1980s, the Conference of Radiation Control Program Directors' QA committee published exposure guides.

In 1978, there was a Federal directive that directed the Federal agencies to follow guidance regarding certain exposure levels for certain examinations.

The Europeans have taken that concept and done a whole lot more with it in the intervening years, and it is sort of coming back to the United States with the American College of Radiology pushing an initiative.

One of the things that we are aware of is that these are great ideas, but how do you measure the

dose, and we thought -- I mean, some of the thinking in the Center is that we need to provide part of the technical fix for this.

DR. NELSON: Right.

SECRETARY SULEIMAN: And allow the users to figure out how to do the dose, because some of these dose calculations, and I hate to say it, but there are probably only a few people who really appreciate what it takes to calculate them for some of the more complicated procedures.

And you don't have the time to spend more -- so much resources to derive the doses for some of these procedures.

DR. NELSON: So would this thing that would be at the operator's console do that for people? Is that what you are proposing?

DR. GAGNE: Well, I wouldn't propose it without a complete program.

DR. NELSON: Sure.

DR. GAGNE: And I think without a complete program associated with public training, and education, in terms of what to do with it, it may not

be that useful.

And so it has to be part and parcel of a total program, I think, in order for it to be or to do some good. But that is the intent though. That is the intent with respect to the reference dose values to have an active program that is feeding back information and not penalizing users, for example, if they are beyond a certain thing.

But just having them reflect on whether in fact they are there because their facility does tough cases, or they are there because maybe they need to come down, you know, and make a decision, a value judgment, and a decision based on all of the facts, and not just the patient exposure, but the kinds of tasks that are being done, et cetera, et cetera

DR. NELSON: All right. So you are proposing that these will be used in two ways. One, which may or may not get implemented, which is at the patient level, and people keep track of doses.

DR. GAGNE: Yes.

DR. NELSON: But another is at the institutional level, and compare them at the

institutions.

DR. GAGNE: Oh, sure. That is the intent, exactly.

DR. MARX: I think there are many reasons not to keep records of individual patient doses. You don't want to discourage people from getting or getting treated for potentially curable diseases, and you don't want to -- well, you want to factor in their potential cancer from the radiation, but god only knows what their limit to their mortality was going to be from the primary disease.

So I think there are a lot of reasons not to go there, but they have a programmatic approach where somebody starts to notice if the performance of an x-ray unit is not as swift, and something systematic there makes a lot of sense to protect the population of patients, and not the individual person.

DR. GAGNE: Because this is really somewhat of a different question than the fluoroscopy issue, which represented deterministic effects and skin burns. Here we are talking about stocastic long range sort of effects, and so it is a little bit

different.

DR. LOSCOCCO: I think I would have to agree that putting a dose on each individual film is not where you want to go, but keeping a log of procedures that have doses associated with it.

DR. CARDELLA: I have been one of the advocates for the dose rate meter and the cumulative dose for interventional procedures, and the notion of putting a dose rate meter on, let's say, a radiographic installation -- when I first thought about it, it had little appeal to me, but over the last 2 or 3 months, we have been doing some studies, and our technologists are getting sloppy in their techniques.

They don't look at technique charts anymore when they use CR or DR, and they produce the x-ray probably at the high end of what they need to use so that they get a good pleasing picture for the radiologist.

And I can see some value to the dose meter if each time the tech snaps a chest x-ray, for example, they look at it and say, okay, I used 12.

Then they go to the radiologist, and the radiologist says that is a great chest x-ray.

So the next time the tech would say I am going to try 10 and see if he still likes it. If they used it in that way, it would be of benefit to rationalize it out. But I am a little skeptical that they would do that.

DR. GAGNE: Are you making some comments on the power shift in terms of who is setting the technique factor?

DR. CARDELLA: It is happening.

DR. GAGNE: I didn't think I was going to get any questions. I don't know is this is good or bad.

MS. KAUFMAN: I don't have a question for you. But actually I wanted to comment on what Dr. Balzano had said. We have a health maintenance network in L.A. County that has gone totally digital, and it is my understanding that one of the, if not the primary, motivations for doing so was cost.

Because what they are hoping to do is eliminate film, and eliminate processors, eliminate

chemicals, and have it all be digital. And they are anticipating a huge cost benefit to doing so.

But, Bob, we require a post-exposure mass readout on nano units. I realize that is not dose, but it is very helpful. We don't require that on radiographic; is that right?

DR. GAGNE: I think that is correct.

MS. KAUFMAN: And so it would seem to me that my understanding is that that is a fairly easy technological thing to do. I mean, we have done it on nano units. So that might be one thing to consider, is at least going to film screens of some sort, and maybe it is applicable to digital, too, and going to a post-exposure mass readout.

DR. GAGNE: Well, it is one piece of the entire equation that would go into a dose calculation.

MS. KAUFMAN: Actually, I think it is not just mass. I think it is any automatic factors that the unit does that it has to give you a post-exposure readout.

DR. RICE: Besides the cost advantage, you also don't have repeats with the digital system. So

in a clinical situation, you may have 5 percent repeats over a given period of time.

That may not sound like much, but if you look at the film bin, where you are collecting these films, that is a lot of excessive exposure to patients; whereas, you don't have that with the digital system. So that is certainly a consideration.

DR. GAGNE: I pointed that out, and that is certainly the assumption that I am operating under without a whole lot of data, however.

MS. KAUFMAN: Well, what we have found in practice that they do is that they just delete those images that they don't like for positioning, or it might not have to do with exposure factors. But they are just gone.

So you don't have a film bin to look at that, and in many situations the technologist can do that, and just no one ever sees those bad images.

CHAIRMAN ROTHENBERG: I think there have to be recommendations with regard to keeping track of those images as well. That is implemented in some systems. Some pix developers have incorporated it and

I think there should be a push to have them do that. That is maybe not coming from here, but in general, and in the radiology community there should be an assessment.

Well, thank you again, Dr. Gagne, and we have many things to consider. Now, we are at the -- well, I guess we have discussed a lot of the technical issues, and I guess now the committee discussion should be what recommendations do we feel that we would like to make, if any, to the Center and the FDA.

DR. SHOPE: I have a conclusion remark.

CHAIRMAN ROTHENBERG: Oh, I'm sorry.

DR. SHOPE: My job was to wrap it up so we can go to lunch, I guess. What I would like to do now is just kind of review for you what we would like the committee's help with. And just to refresh you a little bit, this is sort of the proposal for consideration, or the question in front of us, and it can be split into a couple of pieces probably by looking at CT separately from DR or CR, or other modalities, radiographic systems.

But basically I think we are looking for

input from the committee -- suggestions, observations, comments -- on whether we should look at amending the standard to either require a dose display of information related to patient dose on computed tomography systems.

Should we do something similar for digital radiography systems, for computed radiography systems, or radiographic systems in general, and part of the question then is would such a requirement facilitate those minimalization or optimization in the use of x-ray imaging. Next slide.

A couple of comments related to these issues. There is currently a requirement for dose display in the recent IEC standard for computed tomography as Stan mentioned in his discussion, but there are some concerns about that in terms of the somewhat lose approach that was taken for the helical scanning systems or the multiple slice systems, where it is pretty unspecified as to what that dose display number really means.

But we are aware that the committee responsible for that standard is looking at this issue

and we hope to have some input and some influence perhaps to an improvement in that standard. Next slide.

For radiographic systems requiring a display of dose would be a novel proposal compared to what our historic experience has been. We have had MA meters, KVP meters, post-readout displays on some systems.

Clearly, it looks like with today's modern technology, most of these systems are computerized to some extent. Some kind of dose display or an index related to dose is probably feasible at first glance, but there are a lot of issues and questions that we are the first to admit that we have not explored thoroughly, in terms of what the technical issues are here.

Another question -- and I think those are solvable issues with the current technology. We probably could come up with a proposal that would display a number, and probably not at great expense.

The question would be though is this information useful. Would it be used to help

physicians and facilities improve their practices. So those are some of the questions that we have in front of us. How could we proceed from here. The next slide.

Well, clearly one of the possibilities is the main work of this committee, is that advice on amendments, or changes, or new standards related to radiation safety.

We could begin much more in earnest with the encouragement of the use of diagnostic reference levels, or diagnostic values, or entrance skin exposure guidance, or whatever you want to call it, as part of a facility wide quality assurance program.

We have had some involvement in this over the years, and we have a participating -- Dr. Suleiman is on the AAPM committee that has been working on this report, and so the idea of collecting national data that would allow a facility who wants to implement a diagnostic reliable type concept in their facility to have something to compare to, FDA might do what we can to facilitate that collection of national representative doses.

And perhaps we need to go beyond a few eight or so exams that is next currently looked at to a wider range, or look at a system that would allow the collection of more information for this kind of comparison. The next slide.

We could more actively foster training of users of radiological equipment, and this ranges from the physicians and their training to the technologists, to the medical physicists, and all these areas are some places where we historically had some activity.

And perhaps not as much in recent years as in our earlier times. Another area that we could consider is working with the States, and the joint commission on accreditation of health care organizations, or others, to establish and ensure that there are adequately trained users of this equipment so that for the digital systems there is a better understanding of the implications of how these systems are used. Next.

We could communicate directly with the physicians and health care facilities about some of

these issues; the CT, pediatric dose issue, and the potential for a health advisory there, and bringing these issues to more attention of the users of this equipment.

We might assist the professional associations and even the training institutions to develop some training materials for physicians and others on these issues. And particular, I think, sort of as a carryover from the activity that we have had dealing with fluoroscopic systems and the interventional procedures, maybe we do need more training in the residency programs of non-radiologists physicians about some of these issues.

But for CT and for CR and DR, most of that is done under the perview of the radiologist. But that is also something that can change in the future. Next.

So what are the proposals that we would ask you to consider and give us advice on? Should we amend the standard for what modalities and such amendments needed, and would such a system feature on these systems be useful, be worth the costs, be

implementable, be useable.

And sort of as a final question, what other actions should FDA consider in addressing these problems. You might want to advise us that dose displays are not the way to go, but some of the other options available to us are what we might want to consider putting our emphasis on.

So that is the question I think that we would like some feedback from the committee on. Is that the last slide? I believe it is. Okay. So that is sort of what we would like from the committee.

A little bit beyond the normal advise us on our proposed amendments to the regulatory standard, but more stepping back and taking a slightly bigger picture look at how would FDA and CDRH perhaps get the biggest payoff from our efforts to address what we think are some issues that need some attention currently. So that is our conclusion.

(Discussion off the record.)

CHAIRMAN ROTHENBERG: I don't know that it is here anyway, and so why don't we have some discussion.

MS. KAUFMAN: I wanted to make a general statement before we start our discussion, and that is that I served on other committees like this before, and a lot of the members seem to always think about their own facilities, and their thinking about large facilities that have medical physicists support, and have radiologists.

But one needs to keep in mind that these kinds of standards would apply to all x-ray equipment, and there is a great deal of this equipment that is located in the single practitioner's office, and who is not a radiologist, and who has no medical physicists support, and literally never has a medical physicist or someone else come in and look at what they are doing. So we just need to keep that in mind.

CHAIRMAN ROTHENBERG: Other comments?

MS. KAUFMAN: All right. Well, let me start with the CT one then. I had made a suggestion earlier that -- because I think the FDA probably could tomorrow, and this would not require an amendment to the standards or require any significant changes, would put out an advisory to users about adjusting the

technical factors on CT scanners to adjust for patient size. And I would like to encourage the FDA to put out such an advisory.

CHAIRMAN ROTHENBERG: Is there any discussion on that proposal?

CPT THOMAS: Isn't that standard in practice today to make those adjustments, or am I living in an ivory tower?

MS. KAUFMAN: Most facilities are not doing it. He was saying that the next survey indicated that in the next survey database that 43 percent of them were doing it, which means that 57 percent were not.

But frankly I think that is -- we are not finding that, and I think it is a much smaller number that are making those adjustments.

SECRETARY SULEIMAN: Let me clarify. In the next survey, we ask the question do you use dedicated pediatric techniques, and that question apparently has never been asked on a national sample ever before, and so it is the first time that the question was asked.

Clearly when you are asked a question like that, there may be some bias towards answering in the affirmative. But nevertheless you could argue that that 43 percent is probably a much more realistic estimate of what is reality than anybody else's guess.

So clearly it is not a hundred percent, and clearly why Stan presented it, and clearly we have been discussing this within the center itself whether we should go out with a patient notification -- a notification -- well, whatever the term, right or wrong.

Well, we have different names; public health advisory notification or information notification or whatever. So we have considered that, and I guess we want to hear from the committee formally whether they think it is a good idea.

MS. KAUFMAN: We have been asked the question and I know that 43 percent of our facilities are not adjusting it significantly lower than that.

CPT THOMAS: I want to put on my appointed hat and take the opposite view for discussion purposes for a quick minute.

MS. KAUFMAN: Sure.

CPT THOMAS: I am not sure that an FDA advisory, or a safety note, will benefit the public. I think it will only -- I think it may result in a fear factor of having an examination performed more than it will benefit reducing techniques.

People that are using CT scanners in general -- and again I may be living in the wrong world, but I think they understand the importance of reducing techniques.

Now, the CT survey shows that that is not the case, and that under 50 percent, but my real concern is the concern that was raised a little bit earlier, and that is what is the impact on public perception about having an examination.

The FDA comes out with an advisory that says that this technique provides too high of a dose, and that is the way the press would read it. If we have an FDA safety advisory, then my first reaction would be, well, I don't want my children to go and have this examination without understanding the risks of not having that examination to my children.

MS. KAUFMAN: Well, I sort of object to that paternalistic approach frankly. Number One, I think a lot of it depends upon the FDA advisory would be worded, but I am presuming that it would be phrased in such a manner that we are aware that pediatric doses may be able to be further reduced.

You know, it depends on the way that you phrase it, and I think that for the -- for at least, say, 57 percent of the facilities that aren't doing it, I think that the reason that they are not doing it is not deliberate. I think that they have not thought of it.

And that is what an advisory would accomplish, is getting them to at least think about it. And it can be a pretty significant reduction in dose, and I think patients -- that the few patients who might be come alarmed would be outweighed by the number of patients that would be benefited by facilities thinking about it.

There are an awful lot of CT scanners that are located in private doctor's offices and not hospitals. We have a lot of mobile CT scanners that

are owned by one radiologist, and they are not making these kinds of adjustments. And I think that the benefits would outweigh the risks.

DR. MARX: With respect to the percentages, I think you have to factor in that there is some CT facilities that probably don't scan children at all. So those numbers I think have to be -- that the next survey should flush out the question maybe a little bit.

And then I think the issue of the advisory I think is sort of a double-edged sword, because there will be medical legal cases to arise out of it undoubtedly. I don't know if that is something to promote.

Are there any other ways to get facilities to change their habits without something that is going to make the front page of the Wall Street Journal? I don't know.

MS. KAUFMAN: I think patient care should take precedence over medical legal issues.

SECRETARY SULEIMAN: For clarification, I will share with you the anxiety that has been shared

with me, and I am sure that it will probably come up subsequently.

But some of the facilities -- you know, you have got very upset and anxious parents saying that I don't want my kids to go the very necessary medical examinations. So there is that anxiety that gets created by this.

At the same time the radiation dose issue is real as well. So, speaking for the center, I think if we were to craft something like this, we would be very, very sensitive to these concerns.

DR. MARX: And all of these articles just appeared in AJR within the last few months, correct?

MS. KAUFMAN: Right.

DR. MARX: I mean, is it worthwhile waiting a year and gaging the response to that publicity before -- I mean, it may be that that in and of itself has an increased amount of awareness, and they are sort of pushing a public awareness campaign in the medical community without a public health advisory for a certain period of time may make it unnecessary. I don't know.

DR. RICE: I think a formal report, or a formal questionnaire akin to the census questionnaire should be sent by FDA to every facility that has Cts, and I think that a month or two after that questionnaire, you should do another questionnaire, and I think you will see a dramatic increase in the number of compliant unit facilities.

I think that if we go too close to the public information thing that it is going to blow up in our faces, and I think let's find out exactly who is doing this properly and who is not. I mean, let's get to the finite numbers and I think that if this is a requirement for all units, we will know exactly the absolute numbers.

And then it suggests the things that should be done properly, and I guarantee you that within a month or two that you can do a follow-up, or within a month do a follow-up questionnaire, and I think you will see a profound change in the percentages of compliant units.

DR. MARX: I wanted to just make a comment to your comment, which is that we have actually done

studies where we have researched for -- well, a quick example off the top of my head is the benefits of lowering cholesterol and heart disease.

And there are a number of very, very well done studies that were highly publicized in some of the most prominent journals. And we know from research that it takes about 5 to 8 years after those articles are published before the techniques that are promulgated by those research articles are actually incorporated into medical practice.

So waiting for people to read these articles and then sort of respond to them could take as much as 5 to 8 years. We also know that if we have articles that are of high quality and some sort of advisory is put out shortly thereafter, that rapidly increases the diffusion time into the medical practice.

DR. RICE: Well, reducing the dosage is a sample matter of reducing your MAS, and so anybody who works with Cts would know how to reduce, and just plug in lower numbers for pediatric cases.

And if you give them some sort of

guideline, if we can come to a consensus on a guideline as to what does you should use for certain body weights, then I think that would be implemented without any problem. That is not a big deal.

DR. NELSON: Right. Well, I would argue that it is just as easy to write for 20 milligrams as it is to write it for 10, for example. I mean, we are talking about easy things to do that just seem not to get done for about 5 to 8 years.

And if my understanding is correct, that is what you wanted to do, was to send out some guidelines.

CPT THOMAS: I think another comment is that we were just talking about these articles that appear as if they are only in the AJR. They were quickly picked up and put in USA Today and the Chicago Tribune, and places like that.

So it is not that they are not out there among the public, as well as the medical community. So I think that people are aware of these things in a lot of places now, but still an advisory, properly worded, would more encourage them to take some steps

to address this without necessarily raising these other issues.

DR. MARX: I think that an advisory note, although it may turn up some alarm in the public opinion just forces institutions to respond to it. When the mammography doses started to come out in public, patients were coming into my office and wanting to know what the dose for particular machines were, and that just forced the issue of making sure that you had good quality assurance on that.

DR. ELWOOD: Just a general question from a process perspective. Is there like a trigger point whereby the FDA would issue an advisory? Like if so many people were going to be killed by a certain machine, or maybe is a public health advisory too much. This is a question for you.

SECRETARY SULEIMAN: It is an internal process. Ron, if you want to step up and answer, or stop me when you -- Ron is from our Office of Surveillance.

MR. KACZMAREK: First of all, there is no hard and fast rule and you don't require 1.3 or 1.4

deaths before acting. It is, unfortunately, a subjective process. The second thing is that I think that anytime the agency acts there is that potential to scare people away from a needed examination.

Let me give you an example. In the past, we issued a public health notification on endoscopy because we had evidence that the transmission of infectious agents by endoscopy.

And there was the fear that people expressed that, and there was the chance that patients simply won't go for their needed examinations because they will fear that they made experience an infection that they wouldn't get otherwise.

And, of course, endoscopes are extremely valuable in diagnosing peptic ulcer disease, removing clonic polyps, ex cetera. However, the clear decision was made that in the context of the public health notification the Agency indicated up front that we recognize the incredible value of endoscopy, and that patients who require it clearly should go for those examinations.

And I think that in this case that this

could be handled in a similar fashion. Again, the Agency would state very clearly that there can be tremendous benefits from these CT examinations.

The benefit-risk ratio, when the procedure is medically indicated, can be quite compelling. And therefore I think that those concerns can really be minimized.

DR. SANDRIK: Let me ask. Do you do any sort of follow-up on how successful you are in wording some of these things, in terms of seeing the number of exams drop off after you issue one of these statements, or it doesn't change, or it goes up, or any sort of reaction?

MR. KACZMAREK: In general, the agency does have some procedures by looking at the effectiveness of public health notifications. I don't think the person from that staff is here right now. But certainly in terms of endoscopy, there is no indication that there was a tremendous fall off in procedures, or if that was a significant problem after that particular Public Health notification was released.

SECRETARY SULEIMAN: Okay. Thanks. I do know -- and I don't know if it is standard policy yet, but I do know that on some of the alerts, that on some of the notifications that they have done pre-alert -- you know, trying to assess what the status of people who are going to receive the alert.

DR. MARX: Market testing?

SECRETARY SULEIMAN: Yes, to see -- well, we are constantly asking how effective we are. I mean, it is not just a case of getting up there and talking about it, and talking about it. I think we have to gage whether we are effective, and look at other avenues.

The fluro alert of '94, and yet we still have people who don't know what we are talking about. I was involved with the latex toxicology safety alert way, way back when, and we were concerned that we were going to scare everybody for making it associated with latex.

So that type of question is asked over and over again for all these types of issues. So it would be handled institutionally, and I will put the

credibility of the agency on the line. I think we will do a decent job on it.

But, yes, are some patients going to get scared? Probably yes.

DR. MARX: I think you have addressed my concerns. It might be worthwhile in some ways putting into this thing -- well, I assume that these are sent to facilities? This would be a letter sent to facilities or physicians, or --

SECRETARY SULEIMAN: The target audiences are identified.

DR. MARX: All right. And to some extent we could put in there that they may want to develop a plan to respond to patient concerns.

SECRETARY SULEIMAN: Well, I am sure that all will be discussed; which target groups, and what is the recommended action. We have had cases where we have come up conceptually with recommendations, and then found out that we couldn't propose the recommendations. It would be thoroughly looked at. Ron, is there anything that you want to add to that?

MR. KACZMAREK: I would agree with all your

statements.

MS. KAUFMAN: I just want to emphasize one thing, and that is when we have done CT scanners -- and incidentally we have something like 3 or 4 percent of all the x-ray equipment in the country is located in L.A. County.

So we have a really high or large volume of facilities, and it runs the gamut; from the best facilities to some of the worse. But when we have specifically asked CT users when we have asked the question do you adjust the dose, the technique, and when they say no, we say why not, and almost all of them -- and in fact I don't think we have ever gotten any other response other than you know what, I just had not thought of it.

So I think that is what this advisory would do, would just make people think, gosh, I could do that. I had not thought of it before, and that is a good idea.

DR. LOSCOCCO: When the FDA notice came out for the fluoroscopy lower end, and when you decrease the up maximum on a high dose down to 20,

from unlimited down to 20, did you have any kind of repercussions like Dr. Marx was talking about, about legal medical aspects from previous patients coming back and saying that I was examined under the unlimited dose rules and now I got overexposed by four times?

DR. MARX: The lawsuits that I am aware of is where these are clearly injured patients. We are talking about people with holes in their backs.

SECRETARY SULEIMAN: Two separate issues. The 20-R limit was an amendment that we made to the standard I guess about 10 years ago, and unless someone wants to correct me --

MS. KAUFMAN: In '95. I think that became effective in '95. It was all at the same time.

SECRETARY SULEIMAN: But to the best of my knowledge, nobody ever came forward and said --

DR. MARX: All the same, I think that is pretty esoteric. I mean, clearly patients were clearly injured in those.

SECRETARY SULEIMAN: And the fluro burns was really more of an examination specific type -- or

a bunch of examinations specific.

DR. CARDELLA: I would like to either second that if that was a motion, or propose a motion that the FDA produce a delicately worded health advisory. I wouldn't call it a safety alert.

I would use the health advisory category; to the effect that it has come to our attention that there is an opportunity to further reduce the safe dose level of CT in children and send that out.

MS. KAUFMAN: I will second that motion.

CHAIRMAN ROTHENBERG: Okay. Is there any further discussion on this? Okay. Why don't we vote then. How many people would be in favor of this motion?

(A raise of hands.)

CHAIRMAN ROTHENBERG: Opposed? Abstained? It looks like it is unanimous within the community to go ahead with that.

SECRETARY SULEIMAN: And for the record, we have got all 15 members of this committee here today.

CHAIRMAN ROTHENBERG: I guess the lunches

for those of you who ordered that are here, and so maybe at this point it might be a good idea to break and think about some of the other things that Dr. Shope has brought up.

MS. KAUFMAN: If you would like to work over lunch, I may be the only one who is planning on going out, and I am agreeable if you want to work over lunch.

CHAIRMAN ROTHENBERG: How many people on the committee were planning to go for lunch outside? Okay. You are the only one. Why don't we just take a general 10 minute break, and get a chance to distribute the lunches, and then see if we can continue with some discussion.

(Whereupon, at 12:20 p.m., a luncheon recess was taken.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:05 p.m.)

CHAIRMAN ROTHENBERG: I think we are still doing okay with our schedule, but we would like to get things rolling so that people who have flights to catch, or other commitments later in the day will be able to get to them.

We would like to go back and consider some of the things that we heard this morning about the digital systems and CT systems, and I think that one of the things that I would like to know is about proposals relating to dose displays.

What recommendations do we want to make? I think we shouldn't be specific, but if we want to encourage the Center to go ahead with the investigations relating to the appropriate dose displays, that could be one of the things that we could work on, and then they could report back to us as to the specifics.

Does anyone have a recommendation, or a -- yes, John?

DR. SANDRIK: I guess I will just start

off with a couple of comments. I guess one thing that really has to be set up early on is what is really FDA's intention or goal in providing this dose display.

And I think that a lot of the users of the equipment will have various goals that perhaps are different from yours, but it will be very helpful I think to the manufacturers to know what they need to provide.

And in listening to some of the discussion earlier about having some sort of a dose read out on CT systems, and physicists turn them off because they feel that they are not useful for anything.

So I think it has to be clear what is the use of having this dose display, and what are they going to do with it. For example, some people might want to have relevant to radiation protection type calculations, and that could be a very complicated sort of thing to provide.

Whereas, if you are looking for an output of the x-ray system, basically a watt hour meter or something, an x-ray tube would provide you some sort

of a measure of that.

So I think it has to be clear just what it is that you are trying to provide from the point of view of those who likely would have to provide it. And also as well that as it comes from different manufacturers, and on different pieces of equipment, so that on a CR dose, or dose index, a CR index, a DR index, or maybe a CT index, or whatever, if they are all supposed to be inter-comparable, that they are really defined in a way that they can be inter-comparable if you are seeking that sort of thing.

And as you were talking about before, should it be possible that they can add their CR dose and their DR dose, and all the others, or is there really no intention that that should ever be a part of this index.

So I think it is really a matter of defining what are you going to do with it. The other aspect I think, and which we were discussing a little at lunchtime, is what is the intention that the users are going to do with this.

Is there any intention that a technologist

should be recording this every image, and that there be some sort of a quality control process of a weekly phantom measurement that you trace this with.

Who is going to have this responsibility. Is the physician expected to look at every image as it is being interpreted to see what the dose value was, and is the technologist supposed to do this.

Does the physicist do this on a monthly or annual basis or whatever. So there are a lot of questions as to what it is going to be used for, and who is going to use it.

CHAIRMAN ROTHENBERG: Any comments? Yes, Jerry.

CPT THOMAS: I have had mixed thoughts on the display of doses from radiographic procedures for years, and they have been opposing thoughts. When I put the radiation protection hat on my head, a display of dose is meaningless unless I can attach a risk value to it.

And I am unsure that a display of a dose from CT, CR, or DR, as part of a display, that we can place a risk value associated with that unless we

clearly understand the anatomy that is being irradiated and the organs that are being irradiated.

On the other hand, when it comes to the other side of the fence looking at consistency of performance between types of examinations for giving techniques.

Digital technologies allow us to do an inherent integration of the actual exposure necessary to create that particular medical image, and I see from my radiology department hat viewpoint where I could use that information very proactively in looking at equipment longevity, and equipment performance.

There are a number of things that could be done there. So I am unclear, and I agree with John, but I am unclear what the benefit of this would be, and I think the benefit has to be defined as to who is going to use the data, and how do they plan to use the data.

So I am kind of ambivalent frankly to having a dose display unless we understand clearly what it is to be used for.

CHAIRMAN ROTHENBERG: I would just like to

say a word about the CT dose display. One thing about a CT scanner, particularly now at the multi-slice units, you have a lot of different choices, in terms of pitch, and slice thickness, and your normal technique factors, and I think even if it is just for the person sitting at the console as they change these -- as they make these choices, they can see how the dose figure changes.

And I think right there that you have a valuable relative number, even if it is not exactly the same as certain other dose parameters. In addition, I would want any choice that is made to be consistent with what some of the national and international bodies are recommending in terms of appropriate definitions for these.

So I would encourage the center to -- I would personally like to see them go ahead with recommending this. It is already in place in the European countries, and the same companies are manufacturing those machines anyway.

And then also to make sure that it is consistent, but the definitions themselves are

properly stated, and consistent.

MS. KAUFMAN: I think we need to separate the discussion into CT and other exams, because I see them as different. I absolutely agree with you on CT scans, and I think what also makes me feel that way is that I know in fluro when I would discuss with different physicians what the difference in exposure rate was when they would go, for example, into a magnification mode, most of them really didn't know.

And so I think the same would be true for CT, is that when they make those kinds of changes that I think most of them may not realize the impact that it is going to have on dose. So I would encourage it, and was that a motion on CT scanners, or -- oh, he can't make a motion?

All right. I would make a motion just relative to CT scanners that there be some kind of a display of some indication of dose, and this is deliberately being phased very loosely, because I agree with John that it needs to be fairly clearly defined and it probably needs to correlate with whatever the international community comes up with.

With the understanding that this may not be an absolute dose value that a medical physicist might measure, but it would be some relative point that you could look at and make some comparisons with.

CHAIRMAN ROTHENBERG: Is there a second?

DR. LAMBERT: I don't understand why you would want to exclude the digital.

MS. KAUFMAN: I think it is a little bit more complicated, and I thought that we might be able to come to a better agreement right now on CT, and then we would talk about digital and general radiography next.

I think when you are looking at some of the others -- well, the issue to me has to do again with what John had said, in terms of how it would be used. I see the digital display on CT as being very useful.

For one thing, they are big numbers. It is not a small dose, and I think you will see some significant changes in dose when you go from one technique to another. But I think when we get to digital is where I start having some concerns, in

terms of how useful the information would be. So that's why I felt that we might just want to separate the vote.

CHAIRMAN ROTHENBERG: Okay. So we have a motion. Do we have a second?

DR. BALZANO: (Raised hand.) I second the motion.

CHAIRMAN ROTHENBERG: No further discussion?

DR. CARDELLA: I hope that this doesn't sound like a dumb question, because I have been paying intense attention this morning. Are we talking about host exposure indicator of the dose that was delivered, or are we talking about some mechanism whereby the dose delivered during an anticipated exposure once you dial in the technique is predicted preexposure? What exactly --

CHAIRMAN ROTHENBERG: I think for the moment that that is the current situation with CT. I mean, this is already present on many of the scanners. And this is before you ever turn on the x-rays, and you get a number that comes up to give you an

indication of the dose.

And since this system is not driven by an IEC type device, it is all basically manual selection. So you know what it is going to be. If we do get to the point where we have an AEC type device on CT scanners, then I guess that would have to be -- then there would have to be a post-display as well. Tom, did you have something?

DR. SHOPE: If I may interject. Yes, the current on the books IEC standard which all manufacturers that want to manufacture and sell will probably comply with, does have the requirement for this and an indication of what the dose will be once you have selected those features or those technique factors.

The concern that we have right now is exactly what does that number that they are saying showing mean because of the confusion about some of the terminology and definitions.

So if we got those things straightened out, the IEC standard would do exactly what we are talking about I think here, and it is already on the

books in the voluntary standard.

So one of the things that you might want to think about is do we need a U.S. mandatory standard in addition to the IEC standard to compliment it, to be harmonized with it, and just want is the need here based on what is happening in the international community.

MS. KAUFMAN: Tom, are there no CT scanners that are just manufactured in this country?

DR. SHOPE: As best as I can tell, there is six manufacturers, and they sell worldwide, but that doesn't mean that one couldn't pop up tomorrow.

MS. KAUFMAN: And it could also mean that they might just eliminate that one feature on units that were sold in the United States?

DR. SHOPE: It doesn't make a lot of business sense to me to do that, but it is possible, sure.

MS. KAUFMAN: If they are already doing it, then --

CHAIRMAN ROTHENBERG: The basic motion was to encourage the center to investigate appropriate --

MS. KAUFMAN: Appropriate indications.

CHAIRMAN ROTHENBERG: -- CT dose indicator without --

MS. KAUFMAN: Right, CT dose indicator.

CHAIRMAN ROTHENBERG: -- specifying what it is, because we want it to be consistent with ongoing discussions in the IEC and elsewhere.

MS. KAUFMAN: Yes.

CPT THOMAS: Let me ask a question. Then what you are saying is that you want the dose indicator to be uniform for every device, every CT scanner, whether it is in a single axial or whether it is a multi-slice, or whether it is a spiral acquisition. There are three different acquisitions.

MS. KAUFMAN: I don't know how IEC did that. How did IEC address those different CT types?

DR. GAGNE: Can I comment?

CHAIRMAN ROTHENBERG: Yes.

DR. GAGNE: I think one of the things that Stan was trying to point out is that there is in fact a lot of confusion right now in the community in how to handle non-axial scanning; whether it is multi-

slice or single-slice, spiral CT.

MS. KAUFMAN: Right. You said the whole dose thing was based on an axial scan didn't you?

DR. GAGNE: Yes, that's correct. So that is where the problem lies right now, because things associated with spiral light pitch, the definitions aren't as crisp as they should be in order to get a good understanding of what the appropriate dose descriptive would be.

But in the final analysis, it may not end up being a lot different than what it is now, but it just --

CHAIRMAN ROTHENBERG: Right. Things have to be clarified, but the basic information is there and it has to be tuned.

DR. GAGNE: Right. But I think they really didn't address necessarily any peculiar aspects of spiral, whether single or multi, in their standard, and that is sort of the problem that they are into right now. They are having a meeting at the end of this month to try to resolve some of these issues.

MS. KAUFMAN: If we vote to encourage FDA

to pursue this, I am presuming that you would work in harmony with whatever they are doing, and harmony may not be the right word, but certainly keep abreast of what they are doing.

And it would be years until this was in final regs, correct?

DR. GAGNE: The IEC has a little bit different process than we do.

MS. KAUFMAN: They move more quickly?

DR. GAGNE: I think it is a little bit quicker than our processes, and so I don't think that years is a good estimate for when this will happen.

MS. KAUFMAN: I meant for us.

DR. GAGNE: Oh, yes. And the other thing is that we have commented on their proposals recently. I am a member of the maintenance team for the IEC on CT safety rules, and so we do have obviously some input there with respect to what is going to go into the final regs, in terms of input, but not necessarily the final shape of what this will look like

SECRETARY SULEIMAN: Let me clarify. We have been involved with the IEC, and the IEC has a

voluntary standards process. Unfortunately, it is bogged down a little bit, and I think that has been part of the rationale for us bringing this to the table, because if we were to write a standard, we would definitely open it up to the public, and get input from a lot of organizations, and make sure that the science was very, very sound.

The draft that is on -- it is a draft amendment, and the IEC draft amendment is poorly defined, and it has caused a lot of concern. And actually it is part of the reason why we are bringing you this to the agenda right now.

So we will continue to work with the IEC, but the point is -- and part of it is that if we are paying more attention to this, maybe the IEC will get -- that this specific committee will get their act together a little bit more, in terms of getting their science down more specifically.

MS. KAUFMAN: And let me make it clear that my motion is predicated on the basis that the FDA would make sure that the science was sound on that before they would proceed.

CHAIRMAN ROTHENBERG: Okay. Well, we have had a motion, and seconded, and we have had some discussion on this. I think we can have a vote now.

CPT THOMAS: I have got another question. There are six manufacturers of CT scanners Tom said, I believe, or Bob, or one of the two. Do all of those currently have a dose indication on them?

DR. GAGNE: Well, John could certainly comment, but I would think that if they want to sell on the European market that they will have a dose indicator, and if you are manufacturing for a global market, it will be on your CT systems.

CPT THOMAS: Well, I guess I am concerned that the motion as I have heard it is telling FDA to look into doing what the manufacturers are already doing, with the exception of the fact that it is also clear that the multi-slice and the spiral dose, measurement or displace standard is not consistent, is the what I took away from the talk this morning between the old IEC standard and the new IEC standard.

Now, which one is the applicable standard? I think from that standpoint that I would be willing

to proceed. But if it is what we currently have, then we are not doing anything currently new.

CHAIRMAN ROTHENBERG: I think there are two aspects. One, that even though they have to sell it in the European Market, they don't necessarily have to guess and show that here. I mean, there are ways to turn things on and off with the software.

So we would also be encouraging them to provide the information, and it is possible I guess following this motion that FDA could come back and say that IEC cleared everything up, and all these scanners are going to have this. So there is no need to pursue it.

MS. KAUFMAN: I think if you don't have it here, it is a possibility that here they could say that we will sell you the same CT scanner for $2,000 cheaper, and we just won't hook up this feature or whatever.

CHAIRMAN ROTHENBERG: I think where it is going right now is fairly straightforward. I would like to get a vote on this one, because we still have to consider something that may require more

discussion, and then we still have several other items this afternoon. So if you have one additional comment.

DR. LOTZ: I was just going to say it seems to me that the sense of this motion, too, is along the lines of what Orhan was saying, is that we are just affirming that we think it would be food for FDA to step up and try and resolve these uncertainties about what is displayed in terminology and so forth, and that would be my thought.

CPT THOMAS: Is that the motion that is on the floor? That is not what I heard the motion to be.

MS. KAUFMAN: Yes, because I mentioned about that I wanted them to work in coordination with IEC. So, I was presuming that that was part of it, was to try and get those issues cleared up.

CPT THOMAS: Can you restate the motion?

MS. KAUFMAN: No. You did a great job on that. Do you want to restate my motion?

CHAIRMAN ROTHENBERG: Yes, except that I don't remember exactly what I said. Basically, it was to encourage the Center to pursue a dose indicator on

the CT scanners, and pursue having the manufacturers have a dose indicator on the CT scanners, and having it appropriately formulate to be consistent with other national and international bodies recommendations, as well as --

DR. LOTZ: Meaningful.

CHAIRMAN ROTHENBERG: Yes, meaningful. Does that sound okay? Okay. So do we have a vote at this point? All who are in favor of this?

(A show of hands.)

CHAIRMAN ROTHENBERG: Opposed? Abstained? Okay. It looks like that one was unanimous. Now, the second question with regard to dose displays has to do with the radiograph and digital radiograph systems. So does anybody want to make any motions to get discussion going on that?

DR. BALZANO: I would like to move that the Center -- establish with new technology -- but a benefit to the patient, in terms of either imaging with that and exposure, rather than just having a system that shows an image that might be very well taken, and with x-rays, you can always come up with a

great image, and that is exactly --

DR. CARDELLA: I guess I am not clear on how --

DR. BALZANO: On CR and DR.

DR. CARDELLA: Well, the systems are there, and so what would you have the FDA do?

DR. BALZANO: To compare --

DR. CARDELLA: For a study to compare?

DR. BALZANO: To compare these issues, and some of the -- they don't seem to actually compare with some of the traditional films, and I believe that is incorrect, and -- and make sure that the patient does not get over exposed, as compared to the traditional type of --

CHAIRMAN ROTHENBERG: Do you have a question?

DR. CARDELLA: Are you saying that you would like that investigation to occur before these dose meters are even considered or as a result of them being added?

DR. BALZANO: The point is to get at them, and --

SECRETARY SULEIMAN: Let me clarify. We do have ongoing research, and it is limited. We have other agencies that are involved with research. We have the private sector that is involved in research.

From the medical device side, when the products or devices are approved, a lot of information research data is looked at and evaluated. So I think that your recommendation is nice. It would basically say do what you can regarding this.

But I think that a lot of that type of information, in terms of us trying to fund a study along this line, I don't know. That just is not our primary mission.

I think you are here more in an advice capacity from a regulatory point of view, and what can we do that is different than maybe what research organizations can do. So the advantages of digital versus film screen --

DR. BALZANO: But this technology is really specific to this organization and that is really one of the issues. I thought that was one of the issues that was on the floor.

DR. LAMBERT: I think that is one of the things that we discussed, but I am not sure that is our function.

DR. BALZANO: Well, we need to establish indeed what is the dose --

DR. LAMBERT: I think that John's statement earlier was very appropriate. If you don't know what dosage you are giving the patient, and you just know that you are getting a good picture, you will always crank the exposure up, right?

So having a dose meter or an indication of how this compares with conventional imaging when you take the image would be a very valuable piece of information that the technologist can use to learn from and to model.

CPT THOMAS: Exactly.

DR. LAMBERT: Pardon?

CPT THOMAS: We have got a motion on the floor, and --

CHAIRMAN ROTHENBERG: Is there a second?

CPT THOMAS: I have got a motion that I would like to make. I would move that the committee

recommend to the FDA that in the area of CR and DR that they require industry to provide an indices of the dose to the detector that resulted from a particular examination.

MS. KAUFMAN: I will second that.

DR. CARDELLA: I have the same question now. Now we are talking about a post-exposure.

CPT THOMAS: A post-exposure --

CHAIRMAN ROTHENBERG: Bob, did you have a comment to make?

DR. GAGNE: I hope it is. There has been a little bit of a confusing factor here, because there has not been any discussion at all associated with pre-market review. And what I am saying is that we have not talked about what kind of requirements are needed in order for a device to get pre-market clearance.

Whether it is a flat panel imager, or whatever it is, or even if you want -- they go through a 510(k) process, and if it a full field digital mammography system, it is actually going through a PMA process.